Safety and efficacy of physical restraints for the elderly

Review of the evidence

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OBJECTIVE To critically review evidence on the safety and efficacy of physical restraints for the elderly and to provide family physicians with guidelines for rational use of restraints.

DATA SOURCES Articles cited on MEDLINE (from 1989 to November 1994) and Cinahl (from 1982 to 1994) under the MeSH heading "physical restraints."

STUDY SELECTION Articles that specifically dealt with the safety and efficacy of restraints and current patterns of use, including prevalence, risk factors, and indications, were selected. Eight original research articles were identified and critically appraised.

DATA EXTRACTION Data extracted concerned the negative sequelae of restraints and the association between restraint use and fall and injury rates. General data about current patterns of restraint use were related to safety and efficacy findings.

DATA SYNTHESIS No randomized, controlled trials of physical restraint use were found in the literature. A variety of study designs, including retrospective chart review, prospective cohort studies, and case reports, found little evidence that restraints prevent injury. Some evidence suggested that restraints might increase risk of falls and injury. Restraint-reduction programs have not been shown to increase fall or injury rates. Numerous case reports document injuries or deaths resulting from restraint use or misuse.

CONCLUSIONS Although current evidence does not support the belief that restraints prevent falls and injuries and questions their safety, further prospective and controlled studies are needed to clarify these issues. Information from review and research articles was synthesized in this paper to produce guidelines for the safe and rational use of restraints.

OBJECTIF Procéder à une analyse critique des preuves existantes sur la sécurité et l'efficacité des contentions physiques appliquées aux malades âgés et proposer aux médecins de famille des lignes directrices sur l'utilisation rationnelle de ces contentions.

SOURCE DES DONNÉES Recension des articles listés dans MEDLINE (de 1989 à novembre 1994) et dans Cinahl (de 1982 à 1994) sous l'en-tête MeSH «physical restraints» (contentions physiques).

SÉLECTION DES ÉTUDES Nous avons retenu les articles qui traitaient spécifiquement de la sécurité et de l'efficacité des contentions et de leur mode d'utilisation actuel, y compris la prévalence, les indications et les facteurs de risque. Nous avons identifié et soumis à l'évaluation critique huit articles de recherche originale.

EXTRACTION DES DONNÉES Les données extraites portaient sur les séquelles négatives des contentions et le lien entre l'usage de contentions et les taux de blessures et de chutes. Quant aux données générales sur les politiques actuelles d'utilisation des contentions, elles portaient davantage sur les aspects sécurité et efficacité.

SYNTHÈSE DES DONNÉES Notre recension de la littérature n'a identifié aucun essai randomisé et contrôlé portant sur l'utilisation des contentions. Par ailleurs, une variété de plans d'étude, notamment des vérifications rétrospectives de dossiers, des études de cohortes prospectives et des observations de cas, fournissent peu de preuves démontrant que les contentions préviennent les blessures. Par contre, certains éléments de preuve semblent démontrer que les contentions augmentent le risque de chutes et de blessures. Il n'a pas été démontré que les programmes visant à réduire l'utilisation des contentions augmentaient les taux de chutes ou de blessures. Plusieurs études de cas documentent des chutes ou des décès attribuables à l'utilisation ou à l'abus des contentions.

CONCLUSIONS Bien que les preuves actuelles n'apportent aucun appui à la croyance voulant que les contentions préviennent les chutes et les blessures mais qu'elles remettent plutôt en question leur sécurité, des études prospectives et randomisées doivent être entreprises pour clarifier cette problématique. Cet article est une synthèse des informations puisées dans des articles de recherche et d'évaluation critique afin d'élaborer des lignes directrices sur la sécurité et l'utilisation rationnelle des contentions.

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PHYSICAL RESTRAINT IS DEFINED AS ANY device used to inhibit free movement.[1] Using restraints on combative or confused patients is a widespread practice in hospitals and nursing homes, particularly in North America. Despite the frequency with which restraints are used, their efficacy and safety have rarely been studied.[2] Currently, mechanical restraints are used approximately 500 000 times a day in the United States[1]; most restraints are used on people older than 65.[3]

Many types of devices inhibit patients' free movement: limb restraints, mitts, vests, and wheelchair belts. Bed rails and "geri-chairs" with locking trays could also be considered restraints although they are frequently not viewed as such. Lever et al[4] found that double bed rails were the most commonly used restraint in acute (54%) and chronic care (48%) hospitals.

The prevalence of mechanical restraints depends greatly on the setting, with higher rates consistently seen in long-term care facilities. Lever et al,[4] in a cross-sectional survey of restraint use in several Ontario institutions, found that an alarming number of people were restrained: 78% of patients in a chronic care hospital, 12% of residents in a home for the aged, 35% of patients on a psychiatric ward, and 21% of patients in an acute care hospital. Other estimates of incidence in acute care hospitals range from 7.4% to 22%.[5] In nursing homes, restraints are most commonly used on wheelchairs; in hospitals, patients' beds.[4-6]

Tinetti et al,[6] in a longitudinal cohort study of residents in 12 nursing homes in the United States, found that 66% of residents were restrained at some point during the year-long study. These figures contrast sharply with those from the United Kingdom and much of Europe, where use of restraints is generally condemned. A comparative study revealed that bed rails and physical restraints were used in Canada eight times more often than in Britain.[7]

Macpherson et al[8] surveyed staff on the general medicine wards of an acute care hospital and found that nurses decided on the use of restraints for 76% of patients; physicians had written orders for only 28%. As well, 15% of attending physicians were unaware that their patients had been restrained. Like other studies of restraint use, this study highlighted both the lack of documentation of indications for restraints and how infrequently restrained patients are reassessed. Some studies suggest that restraint initiation and monitoring should remain the domain of nursing staff in hospitals and long-term care facilities.[9]

During the last decade, caregivers, particularly nurses, have tried to decrease the use of physical restraints in North American institutions.[1] Family physicians must consider carefully their use of restraints and develop a rational approach that meets patients' needs for independence and institutions' needs for safety. To do this, they should be aware of the evidence for the efficacy and safety of restraints. This paper reviews the strength of the literature on the efficacy of restraints and the potentially negative consequences of their use.

Data sources and study selection
We searched MEDLINE (1989 to November 1994) and Cinahl (from 1982 to 1994), using the MeSH heading "physical restraints." Use of Cinahl indicated the number of articles about restraints in the nursing literature. Articles initially identified were reviewed carefully to select those pertaining to efficacy or negative consequences of restraints. Only a few original research articles focused on efficacy and safety; we included them all, despite a variety of methodologies. Although articles describing alternatives to restraints were thought to be beyond the scope of this paper, those outlining restraint-reduction programs were used if they looked at the effect of such programs on measures of restraint safety or efficacy.

Given the subject, most studies used retrospective methodology or relied on cohort prospective data. Reports on the negative consequences of restraints, such as nerve injury, strangulation, and death, frequently used case reports and court records. There were no randomized, controlled trials of restraint use for ethical and methodologic reasons. A summary of the main articles and a brief description of their methodology is given in *Table 1*.[9-17]

Table 1. Studies of efficacy and risks of physical restraints

AUTHORS	DESIGN	SAMPLE	OUTCOME	QUALITY OF STUDY
Lofgren et al (1989)[17]	Prospective study of negative sequelae of restraints	102 restrained hospital patients	In-hospital mortality 21%, nosocomial infection rate 12%, new pressure sores 22%. Restraint use more than 4 days increased risk	Lack of control group prevented causal relationship from being established
Rubenstein et al (1983)[12]	Retrospective chart review over 2 years	58 patients at Harvard health service. Mostly young inpatients studied, but patients >60 yrs had 75% of falls	47% of falls occurred while patients were getting out of bed, but 88% had bed rails up at time of fall	Small sample size and retrospective design limited causal effect. Authors suggest RCT* be undertaken to look at bed rail efficacy
Ejaz et al (1994)[14]	Quasi-experimental multiple time series	184 restrained residents of skilled nursing facilities exposed to restraint-reduction program	Nonserious falls increased to equal the fall rate of unrestrained controls. No increase in rate of serious falls	Not an RCT, but prospective and controlled. Suggests some efficacy, but raises ethical questions because removal of restraints did not put patients at higher risk than unrestrained control patients
Powell et al (1989)[13]	Chart review of fall rate and restraint rate before and after restraint-reduction program	160 geriatric medicine patients in teaching hospital	Rate before restraint reduction (per 1000 patient-days): 52 restraints and 7 falls. After: 0.3 restraints and 8.7 falls (not significant)	Not an RCT but took into account confounding variables such as concurrent use of "chemical restraints" and staffing levels
Tinetti et al (1992)[11]	Prospective cohort followed 1 year	397 mobile, unrestrained residents of skilled nursing facilities	31% were restrained; 5% of unrestrained patients had serious falls. Restraint use was associated with injury for entire cohort, including residents at high risk for falls. Regardless of whether restraint use indicated residents at risk, high-risk residents continued to fall despite restraints	Prospective study with adequate sample and control group. Authors tried to adjust analysis for unidentified differences between restrained and unrestrained residents
Schleenbaker et al (1994)[9]	Retrospective chart review of restraint use	323 inpatients on rehabilitation ward	Orders written for 78.3% of patients; restraints used on 32.2% of patients; falls experienced by 25% of restrained and 10% of unrestrained patients; 36% were in restraints at time of fall. Duration of use: fallers, 11 days; nonfallers, 4 days	Finding of increased falls incidental to study. Retrospective study does not allow causal relationship to be established
Robbins et al (1987)[10]	Prospective observational and chart review	222 consecutive admissions to acute care units of a veteran's hospital. 137 patients older than 70, all male	17% were restrained. Mean hospital stay: restrained patients, 20 days; unrestrained patients, 8 days. Restrained patients were eight times more likely to die. Risk factors for restraints: poor mental state, organic brain syndrome, surgery, monitoring devices	Study looked mainly at patterns of restraint use, not at subtle sequelae, such as increased agitation, depression, anxiety, skin breakdown, or pneumonia, because restrained patients were often ill and at risk for these complications regardless. Small numbers and lack of control groups deny association between restraints and mortality rate and duration of stay. Restraints were a marker for frailty
Selikson et al (1988)[16]	Case-control study	34 nonambulatory and 12 independently ambulatory residents of a nursing home	Immobility associated with contractures, severe dementia, history of hip or femur weakness, poor vision (but not because of age), osteoarthritis, mild to moderate dementia	Frequently cited in literature as suggesting link between restraints and complications of immobility, but authors did not include restraints in study because documentation of use was so poor in patient records
Miller (1975)[15]	Case reports	Six elderly patients immobilized by restraints 4 weeks or more for various indications	Decline in mood, physical function, mobility. Increased fear of falling, muscle atrophy, and incontinence were common sequelae	Similar sequelae to those reported by Deitrick (1948) in younger subjects voluntarily immobilized. Case report method not ideal for testing hypotheses about negative sequelae of restraints

*RCT – randomized, controlled trial.

Why restraints are so commonly used

Very few prospective studies have attempted to characterize the indications for physical restraints. Retrospective studies have been hampered by lack of documentation on restraint use in patient charts. Studies suggest that the main reason for using restraints for elderly patients is staff concern for patients' safety, particularly concern that they will attempt to climb out of bed and fall. The second reason is to prevent patients from interfering with treatment or monitoring devices.[6,8,9,18,19] Macpherson et al,[8] however, suggest that restraints are used at times for staff convenience rather than for therapeutic or safety reasons. Other reasons cited include preventing wandering, managing agitation and disruptive behaviour, and maintaining position in wheelchairs.

Cognitive impairment is consistently cited as the most frequent predictor of restraint use in hospitals and nursing homes.[5,6,10,19] Patients with cognitive impairment are generally at risk for accidents, are less able to comply with medical treatments and regimens, and sometimes behave aggressively or disruptively. Various authors have commented on using restraints to punish patients or because of staff frustration.[1,20,21] Although many studies have found that use of restraints increases with age, Gillick et al[22] have suggested that this relationship disappears when cognitive status is considered. In their study, young adults exhibiting confusion were restrained as frequently as confused elderly patients (58.3% vs 52.9%).

Other predictors of restraint use for nursing home patients include older age, female sex, disorientation, use of neuroleptic medications, incontinence of urine or stool, dependence on others to carry out activities of daily living, history of falls, and more frequent participation in social activities.[6] Robbins et al,[10] in a prospective study of elderly patients admitted to medical and surgical wards, found that abnormal mental status, a diagnosis of dementia, surgery, and the presence of monitoring or treatment devices predicted the use of restraints.

Widespread use of restraints is, in part, due to their immediate effect on behaviour, their easy application with a minimum of training, the fact that they often have a modicum of administrative sanction,[19] and the fact that their use is supported by several widespread, firmly entrenched beliefs. Evans and Strumpf[23] examined these beliefs and, by reviewing current literature, attempted to expose them as myths. They identified six basic beliefs: the old should be restrained because they are more likely to fall and seriously injure themselves, we have a moral duty to protect patients from harm, failure to restrain puts individuals and facilities at risk for legal liability, old people are not really bothered by restraints, restraints are necessary because of inadequate staffing, and alternatives to physical restraints are unavailable.

Older patients are at risk. The first fallacy arises from the belief that older adults are frail and more likely to fall. Catchen[24] found that nurses were more likely to restrain older patients than young patients because they thought the elderly were more likely to injure themselves seriously. However, evidence does not support the idea that restraints prevent falls or secondary injury.[1,12,23,24] In England, the hospital fall-to-fracture ratio is 0.7% to 1.7%, a lower rate than in the United States (1.8% to 3.8%), where restraints are more commonly used.[12] Bed rails have not been shown to prevent injury. In a review of 35 falls over 2 years at a Boston hospital, researchers found that almost half involved patients attempting to climb out of bed, 88% of them with the bed rails elevated.[12] The authors suggest that widespread use of bed rails reflects a standard of care based on consensus rather than evidence and advocate a randomized, controlled trial to clarify their efficacy. Restraints used to prevent falls are often ineffective because patients learn to untie them and often fall trying to free themselves.[25] Accidental strangulation of elderly patients by restraining devices has been documented.[13,26-28]

At present, no prospective studies compare injury rates of restrained and unrestrained patients in acute care settings. In an observational cohort study of a nursing home population, however, Tinetti et al[11] found that restrained residents had a fall-related injury rate three times greater than their unrestrained counterparts. Restraint

use was independently associated with injury after adjusting for other factors. Restraints might have contributed to the falls through secondary deconditioning, sensory deprivation, and alteration of gait.

Moral obligation. Belief in a moral obligation to protect patients must take into account that reducing the use of restraints does not increase the rate of falls and injuries. Powell et al,[13] using chart review, documented the efforts of the St Boniface inpatient geriatric unit to decrease the use of physical restraints over 6 years. Despite a decrease from 52 per 1000 patient-days to 0.3 per 1000 patient-days, the rate of falls rose only slightly. Attempts to reduce restraint use in a nursing home in the United States resulted in an increased rate of falls overall, but no increase in fall-related injuries.[14] After removal of restraints, the experimental group of previously restrained residents was found to have a mean weekly rate of falls similar to the unrestrained group.

Legal liability. The legal issues surrounding restraint use can be confusing to health care providers. There is a belief in North America that falls and injuries suffered in institutions could form a case for negligence unless restraints were used. Cases reported in the medical and legal literature have been used to support this view.[29-31] However, lawsuits have also resulted from improper application of restraints, especially when documentation of their use is poor in medical records.[32] Some authors think the litigation risk is higher with misused or unnecessary restraints.[33] Until now, no successful prosecution has occurred in Canada for withholding restraints, only for misusing them.[33]

Not bothered. The belief that restraints do not bother older people is contradicted by observing their behaviour as they struggle to free themselves. In a 1988 study, Strumpf and Evans[34] interviewed restrained patients about their experiences. They found that half the patients, 6 weeks after discharge, reported frequent and distressing recollections of their experience. Patients described feeling anger,

fear, humiliation, resistance, and demoralization. One man described being restrained: "I felt like a dog. It hurt me to have to be tied up. I felt like I was a nobody, that I was dirt. It makes me cry to talk of it. The hospital is worse than a jail."

Inadequate staffing. A common argument is that low staff levels in institutions make restraint use unavoidable. The cross-cultural study by Evans and Strumpf,[7] involving nursing facilities in Britain and the United States, did not support this assertion. Although restraints were used almost six times more frequently in US nursing homes, staffing levels were similar in both places.

Alternatives are unavailable. North American hospitals and staff use a limited repertoire of strategies for dealing with behavioural problems.[34-36] Physical restraints are the first and often only technique used. Evans and Strumpf[36] noted that the average number of alternatives to restraints that US nurses could identify was 1.6 for hospital staff and 2.2 for nursing-home staff. Scottish nurses, by comparison, could name 5.1 alternatives, including physical care (comfort, pain relief, positioning), psychosocial care (remotivation, companionship), activities (recreation, distraction), and environmental manipulation (increased lighting, furniture redesign).

Negative consequences of restraint use

Problems associated with immobility in geriatric patients are well documented. Although these problems are not as well studied for restrained patients, they are a concern for patients whose mobility is limited by restrictive devices.[15,16] Physiologic and biochemical problems include changes in body chemistry, altered metabolic rate, decreased blood volume, orthostatic hypotension, atelectasis, decreased muscle tone and mass, contractures, edema, and bone demineralization.[15,16] Clinically, these alterations predispose individuals to falls, constipation, urinary or fecal incontinence, aspiration pneumonia, pulmonary embolism, decubitus ulcers, and anorexia.[2,17]

The negative psychologic effects of restraints should not be underestimated. Restraints can

make agitated patients more agitated,[1,35] but effects can be more subtle. Patients sometimes feel humiliated because they perceive themselves to be treated like children without control or entitlement.[34,37] Restrained elderly patients report feelings ranging from anger to despair. Some patients have lasting effects of depression and social withdrawal.[34]

Staff working with frail, cognitively impaired patients at high risk for injury often face the dilemma of allowing patient independence and responding to a perceived need for safety. In North America, health care professionals' attitudes to the elderly emphasize safety over individual autonomy. Restricting independence and risk-taking can make stereotypes of elderly people and inhibit attempts at rehabilitation.

Physician's role

Recently, legislators and institutions have put forward guidelines for staff and for protection of patients.[38-40] Table 2[1,2] gives some general principles. Guidelines provide a framework for physicians to become more involved in decisions on use of physical restraints. Physicians are in an excellent position to assess patients when the issue of restraints is raised, with the aim of identifying and treating factors contributing to undesirable and high-risk behaviours. This includes reviewing use of inappropriate or excessive medication and screening for pain, infections, metabolic disturbances, and underlying psychiatric conditions.

Use of standardized assessments of fall risk, such as the SAFE protocol[41] and Tinetti's performance-oriented assessment of balance,[42] might assist in the decision to use restraints or to seek alternatives. If restraints are found to be necessary, physicians can ensure appropriate use and review indications for ongoing need. Advisory physicians and those caring for patients in long-term care facilities should play a role in developing written policies and guidelines for restraint use. Physicians should become educators, stressing the limited value of restraints and the risks associated with their use.

Given concerns about the negative consequences of using restraints and the lack of evidence supporting their effectiveness, using them

Table 2. Guidelines for safe use of physical restraints

Physical restraints should be used in emergency situations when patients' behaviour poses a danger to themselves or others and no alternative is available.

Because restraints have not been shown to prevent falls or control patient agitation, their use cannot be recommended.

Use of restraints should trigger further investigation aimed at removing the underlying problem causing the need for restraint.

Physical restraints could be used to protect medical devices when the use of restraints for this purpose is consistent with the overall goals of therapy.

Restraints should be used only after collaborative decision making between nurses and physicians.

Restraints should be used only after informed decision making by patients, families, or proxy decision makers.

Restraints should never be used as a substitute for surveillance.

Restraints should be used only on a time-limited basis and should be monitored. Staff skilled in their use should check mechanical restraints every 30 to 60 minutes; remove each limb from restraint at least once an hour; and examine restrained patients every 3 or 4 hours for development of negative consequences (eg, pressure sores, abrasions).

Institutions should have written policies for restraint use, including guidelines for consent, types of restraints, physician orders, and monitoring requirements.[1,2]

could be viewed as nonvalidated therapy.[37] As with any therapeutic measure, use of restraints should be governed by patient and family involvement and informed consent. For patients unable to understand and consent to treatment, discussions should be held with substitute decision makers. A decision to refuse restraints once the risks and benefits have been outlined should be respected.[1,37] Good documentation of the informed consent process will help limit liability in cases of patient injury.

These standards of care are in many ways a metaphor for good general medical care of

geriatric patients. The principles of informed consent, open discussion with other disciplines, collaborative decision making, and continued monitoring and reassessment are all features of the good care that family physicians strive to provide. Physicians must assume a larger role in decisions to restrain patients, in ongoing assessment and management of patients requiring restraint, and in development of alternatives to restraints.

Conclusion
The paucity of information on physical restraint use highlights the need to educate physicians about the indications for restraints, the potential dangers of their use, and the ethics of using them. Until now, nurses have been primarily responsible for decisions to use restraints and for continuing assessment of patients in restraints. Now nurses are leading the movement to create restraint-free institutions, mostly because they most feel the conflict among their concerns for patient safety, for patient autonomy, and for their own liability. It is only when physicians become involved, however, that the move to restraint-free care can become reality for many institutions. ■

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